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| APPLICATION NO.                 | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---------------------------------|------------------|----------------------|-------------------------|------------------|--|
| 10/736,448                      | 12/15/2003       | Lars Linden          | WWELL61.002AUS          | 3087             |  |
| 20995                           | 7590 06/20/2006  |                      | EXAMINER                |                  |  |
| KNOBBE MARTENS OLSON & BEAR LLP |                  |                      | KIM, ALEX               | KIM, ALEXANDER D |  |
| 2040 MAIN S<br>FOURTEENT        |                  |                      | ART UNIT                | PAPER NUMBER     |  |
| IRVINE, CA                      | IRVINE, CA 92614 |                      | 1656                    |                  |  |
|                                 |                  |                      | DATE MAILED: 06/20/2006 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del> </del>   |  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|--|
| Office Action Summary  |  | 10/736,448   | LINDEN ET AL.  |  |  |  |
|  |  | Examiner   | Art Unit   |  |  |  |
|  |  | Alexander D. Kim   | 1656   |  |  |  |
|  | The MAILING DATE of this communication app   | pears on the cover sheet with the c  | orrespondence address  |  |  |  |
|  | Period for Reply   |  |  |  |  |  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any   | ORTENED STATUTORY PERIOD FOR REPLICHEVER IS LONGER, FROM THE MAILING DIPLICATION OF THE MAILING DIPLIC | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |  |  |  |  |  |  |
| 1)⊠  | )⊠ Responsive to communication(s) filed on <u>09 December 2005</u> .   |  |  |  |  |  |
| 2a) <u></u> ☐  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |  |  |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |
| Dispositi  | ion of Claims  |  |  |  |  |  |
| 4)⊠  | Claim(s) 1-54 is/are pending in the application  |  |  |  |  |  |
| •  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |  |  |  |  |  |
| 6)   | 6) Claim(s) is/are rejected.   |  |  |  |  |  |
| 7)   | Claim(s) is/are objected to.   |  |  |  |  |  |
| 8)⊠  | Claim(s) $\underline{1-54}$ are subject to restriction and/or  | election requirement.  |  |  |  |  |
| Applicati  | ion Papers   |  |  |  |  |  |
| 9)   | The specification is objected to by the Examine  | er.  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.                                       |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.             |  |  |  |  |  |  |
| Priority (   | ınder 35 U.S.C. § 119  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).                          |  |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |  |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No                                       |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage                    |  |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.                               |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Attachmen  | t(s)   |  |  |  |  |  |
|  | e of References Cited (PTO-892)  | 4) Interview Summary   |  |  |  |  |
|  | e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   | Paper No(s)/Mail Da<br>5) Notice of Informal F   | ate Patent Application (PTO-152)   |  |  |  |
|  | r No(s)/Mail Date  | 6) Other:  |  |  |  |  |

# Page 2

#### **DETAILED ACTION**

## Application Status

1. Claims 1-54 are pending in the instant case.

#### Restriction

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-20, drawn to a method for preparing a solution of refolded eukaryotic membrane protein, classified in class 530, subclass 417.
  - II. Claims 21, 25, 29, 33, 37, 41, 46 and 51, drawn to a crystalline form of eukaryotic membrane protein and a method for preparing a crystalline form of eukaryotic membrane protein, classified in class 530, subclass 350.
  - III. Claims 22, 26, 30, 34, 38, 42, 47 and 52, drawn to a crystalline form of eukaryotic membrane protein and a method for preparing a crystalline form of eukaryotic membrane protein, classified in class 530, subclass 350.
  - IV. Claims 23, 27, 31, 35, 39, 43, 48 and 53, drawn to a crystalline form of eukaryotic membrane protein and a method for preparing a crystalline form of eukaryotic membrane protein, classified in class 530, subclass 350.
  - V. Claims 24, 28, 32, 36, 40, 44, 49 and 54, drawn to a crystalline form of eukaryotic membrane protein and a method for preparing a crystalline

Application/Control Number: 10/736,448

Art Unit: 1656

form of eukaryotic membrane protein, classified in class 530, subclass 350.

Claim 45 link(s) Group II-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 45.

Claims 50 link(s) Group II-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 50.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no

Art Unit: 1656

longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other because of the following reasons:

Group II-V are related to each other by the virtue of a eukaryotic membrane protein crystal and a process of making a membrane protein crystal. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II-V are mutually exclusive, not obvious variant and have different mode of operation to each other because the each membrane protein solution contains different solute. The Group II has a first detergent in a refolding solution and the Group III, IV and V have additional lipid, a second detergent, a low first detergent, respectively.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group II-V are related because the membrane protein prepared by the method of Group I is used in a method of Group II-V. The related inventions are

distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I and Group II-V are mutually exclusive and not obvious variant because the method steps of Group I and Group II-V are different. Because Group I is a method of refolding the protein and Group II-V is a protein crystal, Group I and Group II-V have different mode of operation and function.

Page 5

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

### Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of

Art Unit: 1656

right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Application/Control Number: 10/736,448 Page 7

Art Unit: 1656

#### Election

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/736,448

Art Unit: 1656

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim June 12, 2006

> KATHLEEN M. KERR, PH.D. SUPERVISORY PATENT EXAMINER